

Remarks

Applicant's independent claim 1 is not anticipated by Sahagen U.S. Patent 5,510,895 ("the Sahagen patent"). Claim 1 is a method of performing spectral analysis in a pharmaceutical dissolution process and requires, *inter alia*, inserting a fiber optic probe of a spectral analyzer into a dissolution vessel. The fiber optic probe requires, *inter alia*, a launch cable, a return cable, a launch lens portion, a return lens portion, and a reflector spaced from both of the lens portions. The spacing between the reflector and the lens portion comprises a sample region. The fiber optic probe is sized and adapted to prevent bubbles in the dissolution media from being trapped in the sample region. The Sahagen patent does not disclose claim 1's requirements of: a launch lens portion, a return lens portion, and the fiber optic probe being sized and adapted to prevent bubbles in the dissolution media from being trapped in the sample region.

The Sahagen patent discloses a probe 60 (Fig. 1) having a window 1, fiber optics 4, 5 for transmitting electromagnetic waves, and a reflector 8. A chamber 7 is between the window and reflector for containing a fluid medium. The Patent Office has taken the position that Sahagen's window constitutes a launch lens portion and a return lens portion. However, the dictionary definition for "lens" is:

1. A ground or molded piece of glass, plastic, or other transparent material with opposite surfaces either or both of which are curved, by means of which light rays are refracted so that they converge or diverge to form an image.
2. A combination of two or more such pieces, sometimes with other optical devices such as prisms, used to form an image for viewing or photographing. Also called compound lens.

3. A device that causes radiation other than light to converge or diverge by an action analogous to that of an optical lens.

The American Heritage® Dictionary of the English Language, Fourth Edition, 2000, Houghton Mifflin Company. As made clear by the above definition, a lens is a device that causes light to either converge or diverge. Sahagen's window does not cause light to converge or diverge. Thus, it cannot be considered as including a launch lens portion or a return lens portion. For this reason, the Sahagen patent does not anticipate Applicant's claim 1.

The Sahagen patent fails to disclose a fiber optic probe sized and adapted to prevent bubbles in the dissolution media from being trapped in the sample region. The Sahagen patent provides no disclosure that the Sahagen probe is adapted to prevent bubbles in the dissolution media from being trapped in its chamber 7. In fact, the shape of the Sahagen chamber is conducive for trapping bubbles in that the curved surface of the Sahagen reflector is an ideal place for a bubble to be trapped. Also, the size of the Sahagen chamber is not disclosed. Thus, the Sahagen patent does not disclose claim 1's requirement of a fiber optic probe sized and adapted to prevent bubbles in the dissolution media from being trapped in the sample region.

Claims 4 and 7 depend from claim 1. Thus, claims 4 and 7 are not anticipated by the Sahagen patent for the same reasons that claim 1 is not anticipated.

Claims 2-3, 5-6, and 8-18 are not made obvious by the Sahagen patent in view of Nave U.S. Patent 5,404,218 ("the Nave patent"). The Nave patent discloses a fiber optic probe for light scattering analysis of a gas sample. Exciting light is transmitted into the Nave sample chamber by a first fiber, where the light interacts with the sample to produce Raman-scattered light. At least some of the Raman-scattered light is received

by a second fiber and transmitted to the detector for analysis. The Nave probe does not include a launch lens portion, a return lens portion, and a reflector. The Nave probe cannot be used with liquid samples. Thus, there is no motivation, suggestion or teaching to combine any disclosure of the Nave patent with the disclosure of the Sahagen patent.

Moreover, the Nave patent does not disclose the specific teaching that the Patent Office asserts it discloses. In particular, the Nave patent does not disclose a probe having a cell diameter of 5 mm. Rather, the Nave patent discloses a cell diameter of 0.5", i.e., about 130 mm (Nave, column 7, lines 10-20). Thus, the Nave patent would not motivate one of ordinary skill in the art to employ a cell diameter of equal to or less than approximately 5 mm.

The Patent Office incorrectly relies on the size of Sahagen's fiber optics to conclude that the Sahagen probe is very small. However, patent drawings are not to scale. Therefore, it is not proper to conclude from the Sahagen drawings that the Sahagen sample diameter is equal to or less than 5 mm. Because neither the Sahagen patent nor the Nave patent discloses or suggests claim 2's requirement of a sheath portion having a diameter equal to or less than approximately 5 mm, claim 2 is not made obvious by the Sahagen and Nave patents.

Claim 3 depends from claim 2 and is therefore not made obvious by the Sahagen and Nave patents for the same reasons claim 2 is not made obvious. Claim 3 further requires a diameter equal to or less than approximately 4 mm. This additional requirement of claim 3 is not made obvious by the Sahagen and Nave patents.

Claim 5 requires each cross-sectional dimension of the probe lying in a plane perpendicular to the probe axis and between the reflector and the lens portion to be equal to or less than approximately 5 mm. For at least the reasons discussed above with respect to claim 2, the requirements of claim 5 are not disclosed or suggested by the Sahagen and Nave patents. Thus, claim 5 is not made obvious by the Sahagen and Nave patents.

Claim 6 requires each cross-sectional dimension of the probe lying in a plane perpendicular to the probe axis and between the reflector and the lens portion to be equal to or less than approximately 4 mm. For at least the reasons discussed above with respect to claim 2, the requirements of claim 6 are not disclosed or suggested by the Sahagen and Nave patents. Thus, claim 6 is not made obvious by the Sahagen and Nave patents.

Claim 8 requires the launch lens portion to be generally aligned with an end of the launch cable and requires the return lens portion to be generally aligned with an end of the return cable. The Sahagen and Nave patents, whether considered together or separately, fail to disclose or suggest lens portions at all. Likewise, the fail to disclose or suggest a launch lens portion generally aligned with an end of a launch cable and a return lens portion generally aligned with an end of a return cable.

Independent claim 9 requires, *inter alia*, "each cross-sectional dimension of the probe lying in a plane perpendicular to the probe axis and between the reflector and the lens portion being equal to or less than approximately 5 mm." For the reasons discussed above with respect to claims 2 and 5, the Sahagen and Nave patent fails to

disclose or suggest this claim requirement. Thus, claim 9 is not made obvious by the Sahagen and Nave patents.

Claims 10-13 depend from claim 9 and are therefore not made obvious by the Sahagen and Nave patents for the same reasons claim 9 is not made obvious. These claims are further patentable over the Sahagen and Nave patents because these patents fail to disclose or suggest: (a) the launch lens portion to be generally aligned with an end of the launch cable and requires the return lens portion to be generally aligned with an end of the return cable (claim 10); (b) each cross-sectional dimension of the probe lying in a plane perpendicular to the probe axis and between the reflector and the lens portion to be equal to or less than approximately 4 mm (claim 11); (c) a sheath portion having a diameter equal to or less than approximately 5 mm (claim 12); and (d) the sheath portion having a diameter equal to or less than approximately 4 mm (claim 13).

Independent claim 14 is directed to a method of making a fiber optic probe and requires placing into a sheath a launch cable, a return cable, a launch lens portion, a return lens portion, and a reflector, the launch lens portion being forward of and aligned with the launch cable, the return lens portion being forward of and aligned with the return cable, the launch lens portion having a focal length substantially equal to the focal length of the return lens portion, the sheath having an end margin extending forward from the lens portions and terminating in a sheath end, the end margin of the sheath having at least one slot therein. The method further requires the steps of positioning a reflector element adjacent the sheath end, transmitting light along the launch cable through the launch lens portion and to the reflector element, adjusting the

position of the reflector element relative to the sheath to substantially maximize detection by the detector of the transmitted light reflected from the reflector through the return lens portion and through the return cable and to the detector, and securing the reflector element to the sheath to maintain the reflector element in its adjusted position.

The Sahagen and Nave patents fail to disclose or suggest lens portions at all and therefore fail to disclose and suggest lens portions having substantial equal focal lengths. The Sahagen and Nave patents also fail to disclose or suggest claim 14's step of adjusting the position of the reflector element relative to the sheath to substantially maximize detection by the detector of the transmitted light reflected from the reflector through the return lens portion and through the return cable and to the reflector. Thus, claim 14 is not made obvious by the Sahagen and Nave patents.

Claims 15-18 depend from claim 14 and are therefore not made obvious by the Sahagen and Nave patents for the same reasons claim 14 is not made obvious.

Newly added claims 19 and 20 depend from claims 1 and 9, respectively. These claims require the launch lens portion to be spaced from the launch cable and the return lens portion to be spaced from the return cable. The Sahagen and Nave patents fail to disclose or suggest lens portions at all. For the reasons discussed above, the Sahagen window cannot be considered a lens. Moreover, the Sahagen patent discloses that the fiber optics and the window 1 are in contact with one another. For these reasons, newly added claims 19 and 20 are patentable over the Sahagen and Nave patents.

For the foregoing reasons, claims 1-20 are patentable over the prior art of record. Thus, Applicant requests the Patent Office to withdraw all rejections and to issue a notice of allowance.

DEC 24 2003 10:31 FR THOMPSON COBURN LLP 5314 552 7000 TO 3073#66581#01864 P.16/16

Respectfully submitted,

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